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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/507,968 | 02/22/2000 | Guo-Liang Yu | PF343P3 | 2764 |

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EXAMINER

BUNNER, BRIDGET E

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 07/07/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/507,968

Applicant(s)

YU ET AL.

Examiner

Bridget E. Bunner

Art Unit

1647

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 04 June 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 26-28, 31-34, 36-38, 124, 125, 134-137, 139-143, 152-155 and 157-159.

Claim(s) objected to: _____.

Claim(s) rejected: 35, 39-41, 44, 45, 48-81, 83-123, 126-133, 138, 144-151, 156, 160-213, 215-223, 225-238, 240-341 and 343-429.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 21.
10. ☐ Other: _____

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Continuation of 2. NOTE: The change in dependency of claims reciting "wherein the protein is cytotoxic to Neutrokin- α receptor bearing cells" would raise new issues under 35 U.S.C. § 112, first paragraph. The proposed amendment would change the scope of some of the claims. Specifically, the amended claims would recite that radiolabeled neutrokin- α is cytotoxic to neutrokin- α receptor bearing cells. However, the original claims recite that neutrokin- α itself is cytotoxic to neutrokin- α receptor bearing cells. Therefore, the proposed claim amendments would raise a new issue under the enablement rejection.

If the amendment of 04 June 2003 had been entered, the objection to claims 215 and 343 would have been withdrawn in view of the claims amendments.

If the amendment of 04 June 2003 had been entered, the rejection of claims 39-41, 44-45, 48-81, 83-123, 126-127, 130-131, 144-145, 148-149, 160-213, 215-223, 247-272, 274-275, 278-279, 290-342, 343-429 under 35 U.S.C. § 112, second paragraph would have been withdrawn in view of the claim amendments to remove the term "modulates".

If the amendment of 04 June 2003 had been entered, claims 35, 39-41, 44-45, 48-56, 74, 99, 120, 128, 132, 138, 146, 150, 156, 160-161, 164, 168, 170-179, 182, 186, 188-195, 209, 228, 264, 286, 290, 293, 297, 299-307, 310, 314, 316-323, 337, 356, 366, 370, 378, 382, 386, 390, 410, 414, and 426-429 would have been rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for (i) an isolated protein comprising an amino acid sequence that is 90% or 95% or more identical to an amino acid sequence selected from the group consisting of: (a) the amino acid sequence of amino acid residues 1 to 285 of SEQ ID NO: 2; and (b) the amino acid sequence of amino acid residues 73-285 of SEQ ID NO: 2; wherein said protein induces B cell proliferation, differentiation, and survival and (ii) any isolated protein comprising at least an amino acid sequence that consists of amino acids 134-285 of SEQ ID NO: 2, wherein said protein induces B cell proliferation, differentiation, and survival, does not reasonably provide enablement for all the protein derivatives and fragments as recited in the claims. Applicant asserts that the specification discloses that neutrokin- α promotes lymphocyte proliferation, differentiation, and survival (paragraphs [005], [0023], [0153-0154], [0156] and examples 6-7). Applicant also indicates that post-filing date data substantiate that neutrokin- α stimulates lymphocyte proliferation, differentiation, and survival. Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, the Examiner acknowledges that the specification and post-filing date references indicate that neutrokin- α stimulates B cell proliferation, differentiation, and survival and activates T cell proliferation and differentiation. However, Huard et al. (J Immunol 167: 6225-6231, 2001) state that an increase in T cell survival upon activation was not detected in the presence of neutrokin- α [BAFF] signaling (pg 6230, last paragraph). Therefore, the state of the art is such that it does not support the claim limitation that neutrokin- α stimulates both B and T cell (lymphocyte) survival.

Additionally, it is noted that the specification does not teach that radio-labeled neutrokin- α is cytotoxic to neutrokin- α receptor bearing cells. The specification also does not teach that neutrokin- α alone is cytotoxic to neutrokin- α receptor bearing cells. The examples in the specification utilizing B cells are not adequate guidance, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. The skilled artisan must resort to trial and error experimentation to determine if radio-labeled neutrokin- α is able to bind to neutrokin- α receptor bearing cells and cause the cells to die. Such trial and error experimentation is considered undue.

If the amendment of 04 June 2003 had been entered, claims 160-161, 164, 168, 170-179, 182, 186, 188-195, 290, 293, 297, 299-307, 310, 314, 316-323, 386, 390, 410, 414, and 426-429 would have been rejected under 35 U.S.C. § 112, first paragraph, written description, for the reasoning set forth above for the enablement rejection.